

(1) Protein content, as $N \times 6.25$, shall not be less than 90 percent by weight of the final product, as determined by the method described in section 2.057, Improved Kjeldahl Method for Nitrate-Free Samples (20)—Official Final Action.

(2) Moisture content shall not be more than 10 percent by weight of the final product, as determined by the method described in section 24.003, Air Drying (1)—Official First Action.

(3) Fat content shall not be more than 0.5 percent by weight of the final product, as determined by the method described in section 24.005, Crude Fat or Ether Extract—Official Final Action.

(4) Solvent residues in the final product shall not be more than 5 parts per million of hexane and 3.5 percent ethanol by weight.

[46 FR 38072, July 24, 1981, as amended at 47 FR 53344, Nov. 26, 1982; 54 FR 24897, June 12, 1989]

§ 172.345 Folic acid (folacin).

Folic acid (CAS Reg. No. 59-30-3), also known as folacin or folate, may be safely used in food as a nutrient in accordance with the following prescribed conditions:

(a) Folic acid is the chemical *N*-[4-[[[2-amino-1,4-dihydro-4-oxo-6-pteridiny]methyl]amino]benzoyl]-*L*-glutamic acid.

(b) Folic acid meets the specifications of the "Food Chemicals Codex," 4th ed. (1996), pp. 157-158, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies are available from the National Academy Press, Box 285, 2101 Constitution Ave. NW., Washington, DC 20055 (Internet address "<http://www.nap.edu>"), or may be examined at the Center for Food Safety and Applied Nutrition's Library, Food and Drug Administration, 200 C St. SW., Washington, DC, or at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

481 North Frederick Ave., suite 500, Gaithersburg, MD 20877-2504, or examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) Folic acid may be added to foods subject to a standard of identity established under section 401 of the Federal Food, Drug, and Cosmetic Act (the act) when the standard of identity specifically provides for the addition of folic acid.

(d) Folic acid may be added, at levels not to exceed 400 micrograms (μg) per serving, to breakfast cereals, as defined under §170.3(n)(4) of this chapter, and to corn grits at a level such that each pound of corn grits contains not more than 1.0 milligram of folic acid.

(e) Folic acid may be added to infant formula in accordance with section 412(i)(1) of the act or with regulations issued under section 412(i)(2) of the act which are codified in §107.100 of this chapter.

(f) Folic acid may be added to a medical food, as defined in section 5(b)(3) of the Orphan Drug Act (21 U.S.C. 360ee(b)(3)), at levels not to exceed the amount necessary to meet the distinctive nutritional requirements of the disease or condition for which the food is formulated.

(g) Folic acid may be added to food for special dietary use at levels not to exceed the amount necessary to meet the special dietary needs for which the food is formulated.

(h) Folic acid may be added to foods represented as meal-replacement products, in amounts not to exceed:

(1) Four hundred μg per serving if the food is a meal-replacement that is represented for use once per day; or

(2) Two hundred μg per serving if the food is a meal-replacement that is represented for use more than once per day.

[61 FR 8807, Mar. 5, 1996, as amended at 61 FR 27779, June 3, 1996; 64 FR 1758, Jan. 12, 1999]

§ 172.350 Fumaric acid and salts of fumaric acid.

Fumaric acid and its calcium, ferrous, magnesium, potassium, and sodium salts may be safely used in food in accordance with the following prescribed conditions:

(a) The additives meet the following specifications:

(1) Fumaric acid contains a minimum of 99.5 percent by weight of fumaric acid, calculated on the anhydrous basis.